DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 17, 2015

Best Theratronics Limited
% Mr. Mike de van der Schueren
Quality & Regulatory Manager
413 March Road
Ottawa, Ontario K2K 0E4
CANADA

Re: K150191
Trade/Device Name: GammaBeam 500
Regulation Number: 21 CFR 892.5750
Regulation Name: Radionuclide radiation therapy system
Regulatory Class: II
Product Code: IWB
Dated: February 18, 2015
Received: February 19, 2015

Dear Mr. de van der Schueren:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150191

Device Name
GammaBeam 500

Indications for Use *(Describe)*
A Cobalt Teletherapy unit is a device by which gamma radiation is delivered for the treatment of cancer under the direction of health care professionals in a radiation therapy clinic.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

Date Summary Prepared	January 23, 2015
Submitted by	Best Theratronics 413 March Road Ottawa, Ontario K2K 0E4 Canada Tel. (613) 591-2100 Fax. (613) 592-5680
Contact Person	Mr. Mike de van der Schueren Quality & Regulatory Manager
Trade Name	GammaBeam 500
Common Name	Cobalt Teletherapy Device
Classification Name	Radionuclide Radiation Therapy System
Legally Marketed Predicate Device	Theratron Phoenix (K863180)
Device Classification	Class II, 21 CFR 892.5750
Product Code	IWB

DESCRIPTION OF DEVICE

The GammaBeam 500 is a radiotherapy treatment unit with a cobalt-60 radiation delivery system that is designed to be a dedicated, standalone device for performing total body irradiation (TBI). The device consists of a source head, main frame, base, and controls. The design of this device is substantially equivalent to the predicate device Theratron Phoenix.

The GammaBeam 500 is aimed to deliver total body irradiation to patients by generating a large fixed radiation treatment field at an extended Source – to – Skin Distance (SSD). This is a common radiotherapy technique performed by many clinics worldwide. A dedicated device improves the safety, effectiveness and clinical workflow of these treatments.

The unit will be operated in a similar manner as the predicate and has the same redundant mechanisms for safety, auxiliary source drawer lock, secondary and manual source return, emergency stop switches on the unit and control console, source position indicator, and operational and inhibit state interlocks.

INTENDED USE OF DEVICE

A Cobalt Teletherapy unit is a device by which gamma radiation is delivered for the treatment of cancer under the direction of health care professionals in a radiation therapy clinic.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The GammaBeam 500 is substantially equivalent to the predicate device (K863180).

This GammaBeam 500 includes several changes to the design of Phoenix teletherapy unit.

Device Characteristic	Predicate Device	Proposed Device
Control System	Single computer in control room	Separate main controller and graphic user interface that performs same functionality with added safety features, improved useability and battery backup
Treatment Mode	Rotational and/or fixed treatments with a variable field size	Fixed treatments only and fixed field size reduces complexity and eliminates collision hazards and hazards related to treatment setup
Patient Table	Vertical, longitudinal, lateral and isocentric positioning of the patient	Optional accessory - Vertical motion only for ease of lowering patient to the treatment height from a comfortable seated position

Usability is being improved by adding functions relevant to contemporary cancer treatment techniques and removing those that are not.

The major components of the Theratron Phoenix, including the head, source mechanism, main frame and base have had minor modifications to accommodate the above changes.

There are no changes to the mechanical structure or radiological shielding of the head.

The irradiation source and radioactivity of the cobalt-60 source remains unchanged as does the source drawer mechanism.

The control system has been designed to meet the same intended use as the current model.

PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the GammaBeam 500, consisting of the main unit and patient couch. The system complies with the following standards for safety:

- IEC 60601-1:2013 Edition 3.1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2007 Edition 3.0 Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests
- EN 60601-2-11:2011 Edition 3.0 Medical electrical equipment – Part 2: Particular requirements for the safety of gamma beam therapy equipment
- EN 61217 (2014) Radiotherapy equipment – Coordinates, movements and scales

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". The software for this device was considered as a "major" level of concern, since a failure or latent flaw in the software could directly result in a serious injury or death to the patient or operator.

Mechanical Testing

The performance of the device was tested against a set of functional specifications in an environment that simulated, as much as possible, the actual operating environment. This included:

- Mechanical validation of the main unit and patient couch
- Physics validation
- Simulated use testing

CONCLUSIONS

The non-clinical data support the safety of the device and the hardware and software verification and validation demonstrate that the GammaBeam 500 performs as intended in the specified use conditions. The performance data demonstrates that the GammaBeam 500 is as safe and effective as the predicate device that is currently marketed for the same intended use.